



DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT
93748

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2nd and Chestnut Streets
Philadelphia, PA 19106

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01-PHI-08

WARNING LETTER

February 16, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Barry M. Fabius, M.D.
Medical Director
Sidney Hillman Medical Center
2116 Chestnut Street
Philadelphia, PA 19103

Re: Inspection ID: 1358480006

Dear Dr. Fabius:

We are writing to you because on February 1, 2001, your mammography facility was inspected by a representative from the Commonwealth of Pennsylvania, acting in behalf of the Food and Drug Administration (FDA). Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

This inspection revealed the following level 1 and level 2 noncompliances:

Level 1 Inspection Finding:

Quality Assurance – Equipment: Weekly Quality Control Tests [21 CFR 900.12(e)(2)]

“Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.....”

OBSERVATION: Phantom QC records were missing for six weeks for the [REDACTED] mammography unit.

The inspector found that the phantom image test was not performed for six weeks during the twelve-week time period of September 3, 2000 through November 25, 2000. These weeks were 9/3, 9/24, 10/15, 10/29, 11/12, and 11/19/2000. Additionally, the phantom image test was not performed during the weeks of 4/30, 7/9, 7/30, 12/3/2000.